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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,486	11/13/2003	David A. Schechter	2876	8330

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UNITED STATES SURGICAL,
A DIVISION OF TYCO HEALTHCARE GROUP LP
195 MCDERMOTT ROAD
NORTH HAVEN, CT 06473

EXAMINER

TOY, ALEX B

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,486

Applicant(s)

SCHECHTER ET AL.

Examiner

Alex B. Toy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/12/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on February 23, 2007. The 35 U.S.C. 112, first paragraph rejection of claim 22 is withdrawn in view of applicant's amendment. All previous prior art rejections are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-8, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan (U.S. Pat No. 6,932,816 B2) in view of Hooven (U.S. Pat. No. 6,086,586).

Regarding claim 1, Phan discloses a tissue or vessel sealing instrument, comprising:

a housing 242 having a shaft (internal and not shown) attached thereto (col. 2, ln. 46-65 and Fig. 34); and

an end effector 22, 24 assembly attached to a distal end of the shaft, the end effector assembly including first 22 and second 24 jaw members attached thereto made from a substantially rigid material (col. 5, ln. 61 – col. 6, ln. 2, col. 17, ln. 16-17, and Fig. 5), the jaw members being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween (Figs. 4-5);

each of the jaw members including an elastomeric material 106 disposed on an inner facing tissue contacting surface thereof (col. 6, ln. 32-35 and Figs. 4-8), each of the elastomeric materials including an electrode 108 disposed therein, the elastomeric material being adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi; and

wherein the substantially rigid material of the jaw members resists deformation when the force used to close the jaw members is between about 40 psi to about 230 psi.

Since the elastomeric and rigid materials of Phan are identical to applicant's disclosed materials, they are deemed to inherently, or at least obviously, possess the same material properties at the claimed compression force range.

The claim differs from Phan in calling for the electrodes to be offset a distance X relative to one another such that when the jaw members are closed about the tissue

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and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces. Hooven, however, discloses jaw members with electrodes 42, 44, 46, 48 arranged as claimed so that the flow of current between the electrodes naturally stops when coagulation is complete to prevent thermal damage due to over-coagulation outside the jaws (col. 1, ln. 29 – col. 2, ln. 8, col. 4, ln. 30-45, and Figs. 5-6 and 9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have arranged electrodes on the device of Phan as claimed in view of the teaching of Hooven so that the flow of current between the electrodes naturally stops when coagulation is complete to prevent thermal damage due to over-coagulation outside the jaws.

Regarding claim 2, Phan further discloses that the elastomeric material 106 is silicone and/or polyurethane (col. 6, ln. 32-35 and Figs. 4-8).

Regarding claim 3, Hooven further discloses that the offset distance X is in the range of about 0.005 inches (0.127 mm) to about 0.200 inches (5.08 mm) (col. 4, ln. 63-65 and Fig. 9).

Regarding claims 4 and 5, Phan further discloses at least one temperature sensor 146 which provides information to a feedback circuit for regulating the electrosurgical energy through the tissue (col. 10, ln. 54 – col. 11, ln. 20 and Figs. 7a).

Regarding claim 7, Phan further discloses that at least one of the jaw members includes at least one electrode 108 across the width thereof and the electrosurgical instrument includes means for selecting one of the electrodes for electrically opposing

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the electrode disposed on the other of the jaw members, wherein the means includes a sensor which measures at least one of tissue impedance, tissue temperature, and tissue thickness (col. 11, ln. 21-49 and Figs. 13 and 16a-b)

Regarding claim 8, since the elastomeric materials of Phan are identical to applicant's disclosed materials, they are deemed to inherently, or at least obviously, possess the same claimed comparative tracking index value.

Regarding claim 21, see the preceding rejections of claims 1 and 2.

Regarding claim 22, see the preceding rejections of claims 1 and 3.

Regarding claim 23, see the preceding rejection of claim 1. The claim differs from Phan in view of Hooven in calling for the distance X to be variable depending on the thickness of the tissue between the jaw members. Hooven teaches varying the offset distance X between 1 mm and 6 mm but does not specifically disclose varying the distance based on the thickness of the tissue between the jaw members. It would have been obvious and intuitive to one of ordinary skill in the art, however, that tissue thickness affects the separation distance of the electrodes that is required for effective treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distance X of Phan in view of Hooven variable depending on the thickness of the tissue between the jaw members.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Regarding independent claims 1 and 21-23, applicant first argues that Phan does not disclose an elastomeric material disposed on an inner facing tissue contacting surface of each jaw member. In response, the examiner maintains that a large portion of elastomeric base member 106 is disposed on an inner facing tissue contacting surface of each jaw member as claimed (col. 6, ln. 32-35 and Figs. 4-8). Figure 8, a cross-section of Fig. 7a, clearly shows that elastomeric base member 106 encompasses the electrode 108 and forms a large surface area surrounding the electrode that contacts tissue on the inner surface of each jaw member.

Next, applicant argues that Phan does not disclose that the elastomeric material is adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi. In response, the examiner maintains that since the elastomeric and rigid materials of Phan are identical to applicant's disclosed materials, they are deemed to inherently, or at least obviously, possess the same material properties at the claimed compression force range. Applicant has not provided any structural or material limitations in the claims that define over the structure and materials of Phan.

Finally, applicant argues that there is no motivation to combine Phan and Hooven. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

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the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the teaching, suggestion, and motivation are found in Hooven's disclosure that arranging the electrodes as claimed allows the flow of current between the electrodes to naturally stop when coagulation is complete, which prevents thermal damage due to over-coagulation outside the jaws (col. 1, ln. 29 – col. 2, ln. 8, col. 4, ln. 30-45, and Figs. 5-6 and 9). That Phan teaches one way of arranging the electrodes does not preclude the fact that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have arranged the electrodes of Phan as claimed in view of a teaching in the prior art (i.e. Hooven). Applicant should further note that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT AT
4/30/07


MICHAEL PEFFLEY
PRIMARY EXAMINER
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